EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH LEGISLATION AMENDMENT (MAXIMUM DISPENSED QUANTITIES) INSTRUMENT 2024
PB 14 of 2024

Purpose

The purpose of this legislative instrument is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Main Listing Instrument) to increase the maximum dispensed quantity (MDQ) for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS.

These changes will commence on 1 March 2024, as the second of three stages of implementation of the MDQ measure. Stage 2 includes some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis.

This instrument applies increased maximum dispensed quantities to 238 PBS items to implement the second stage of medicines approved for listing with an increased MDQ.

Authority

Amendments to the Main Listing Instrument

Section 84AF of the Act enables the Minister to determine the responsible person for a brand of a pharmaceutical item. The responsible person is to be the person who has notified the Minister they are, or will be, the person who is, or will be, the supplier of a particular brand of a pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand.

Section 84AK of the Act enables the Minister to determine the pack quantity for a brand of a pharmaceutical item.

Section 85 of the Act enables the Minister to:

- declare drugs and medicinal preparations to be drugs or medicinal preparations to which Part VII applies (subsection 85(2)). A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug';
- determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3));
- determine the manner of administration of a form of a listed drug (subsection 85(4));
- determine a brand of a pharmaceutical item (subsection 85(6));
- determine that a brand of a pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items, for the purposes of paragraph 103(2A)(b) of the Act (subsection 85(6A)); and
- determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit (subsection 85(7)).

Section 85A of the Act enables the Minister to:

- determine the maximum quantity or number of units of a pharmaceutical item in a pharmaceutical benefit that may, in one prescription, be directed to be supplied to a patient on one occasion (paragraph 85A(2)(a));

- determine the maximum number of occasions on which the supply of a pharmaceutical benefit may, in one prescription, be directed to be repeated (paragraph 85A(2)(b)); and
- determine that particular conditions must be satisfied when writing a prescription for the maximum quantities and repeats (subsection 85A(2A)).

Section 88 of the Act enables the Minister to determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)) and authorised nurse practitioners (subsection 88(1E)).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Background – Maximum Dispensed Quantity

The MDQ is the maximum number or quantity of units of a pharmaceutical benefit that can be prescribed for a particular purpose for supply to a patient on the one occasion under the PBS. Currently, the MDQ for many PBS medicines used in the treatment of chronic medical conditions equates to one month's supply.

In December 2022, the PBAC considered and provided advice to the Minister for Health and Aged Care on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased quantity for selected PBS medicines - two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) of the PBS listed for use in treatment of chronic conditions for suitability for the proposal. Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that over 300 medicines were acceptable for listing with increased MDQ. The PBAC also agreed on standard restriction wording for all medicines included in this proposal, to ensure the higher MDQ items are only prescribed to patients whose condition is stable.

Schedule 1 to the *National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024* amends the listings of 238 PBS items to implement stage 2 of MDQ.

New PBS items with the increased MDQ will be included in the Schedule of Pharmaceutical Benefits in addition to the medicine's current PBS items that provide for one month's supply and five repeats (in general). This will facilitate prescribing of smaller quantities than the new MDQ for patients as clinically appropriate, to avoid medicine wastage and support closer clinical monitoring of patients where required.

The PBAC considered this proposal would allow clinicians to exercise greater choice to prescribe the increased MDQ if clinically appropriate and provide patients with both financial and convenience benefits. The PBAC also considered allowing either two or three months' supply for dispensing on the one occasion was safe for the list of recommended medicines and considered that the implementation of increased MDQ allowing two or three months' supply was a decision for the Australian Government.

The Minister for Health and Aged Care announced the Government's intention to implement the two-month MDQ proposal on 26 April 2023 as part of the 2023-24 Budget. The PBAC's advice from December 2022, including a full list of the PBS items considered by PBAC as suitable for an increased MDQ, was published on the same day.

The Minister, in announcing the measure, highlighted the reforms would deliver important and immediate cost of living relief to Australians with chronic health conditions. The Minister announced the Government's decision to implement the policy in three stages, with increased MDQ applied to the first set of medicines from 1 September 2023, to the second set of medicines from 1 March 2024 and to the remaining set of medicines from 1 September 2024. Phased introduction of MDQ will allow the pharmacy sector additional time to adjust to the new practices required to implement these changes.

Implementation of the second stage of MDQ has been designed to maximise the financial and convenience benefits for the greatest number of patients and to deliver these benefits at the earliest possible opportunity. The medicines in stage 2 include PBS items for diabetes, epilepsy, osteoporosis and arthritis, chronic medical conditions that affect many Australians.

An increase in the MDQ for certain medicines used in treating chronic conditions will improve access to and affordability of PBS medicines. It will also mean that patients with chronic, stable medical conditions will need to make less visits to a pharmacy and their prescriber for some common PBS medicines. It will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people. Recent public representations and discussion have indicated broad support from prescribers and consumers for the policy.

Evaluation of MDQ and stakeholder impacts

The Department has committed to developing a comprehensive evaluation framework that will monitor risks and provide mitigation strategies over the course of implementation. This will utilise existing data sources (including PBS claims data) to analyse uptake rates of increased MDQ items, medicine shortages, pharmacovigilance and medicine wastage.

Lower health care costs for patients and Government and maintenance of patient safety will be evaluated by reviewing the PBS statistics for MDQ PBS items. Once sufficient PBS data is available, the utilisation of the new MDQ PBS items and the quantity of medicine dispensed will be monitored and the savings for consumers will be quantified through research conducted by the PBS Post-Market Review program. These utilisation reviews will be considered by the Drug Utilisation Sub-Committee (DUSC) of the PBAC, and any concerns referred to the PBAC.

The Department's planned evaluation framework will utilise existing well-developed processes within the Therapeutic Goods Administration (TGA) and the PBS program to assess outcomes of the implementation of MDQ on patient safety, optimal use of medicines and to identify/evaluate any previously unreported adverse reactions to MDQ medicines (pharmacovigilance). The TGA will continue to monitor all spontaneous reports of adverse medicine events and will inform the Department and the PBAC of any emerging trends in adverse reactions or medicine misuse associated with these medicines.

The Department has committed to evaluating the impacts of MDQ on all affected stakeholders through existing mechanisms. The impact on the community pharmacy sector remuneration and continued participation in community pharmacy programs will be monitored through the existing Seventh Community Pharmacy Agreement (7CPA) till expiry and the new Eighth Community Pharmacy Agreement (8CPA), once effective. The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 7CPA until expiry, and then the 8CPA. Evaluation of financial impacts will be dependent on affected stakeholders providing necessary financial information at a granular level. The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

Commencement

Schedule 1 commences on 1 March 2024. Schedule 1 amends the Main Listing Instrument to implement the second stage of the MDQ measure.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine

on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

Extensive consultation took place in relation to the amendments made by Schedule 2 of the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* to implement stage 1 of MDQ.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

The government has considered current shortages in determining the medicines included in Stage 2. Medicines have been considered suitable for implementation of the increased MDQ measure on 1 March 2024 if they have premium-free alternative brands of the same form that are substitutable by the pharmacist (based on the shortages reported to TGA in one, or more, brands, of one, or more, forms at 2 January 2024).

A full list of the medicines, including forms and PBS item codes, for which an increased MDQ will be implemented on 1 March 2024 for all brands listed on the PBS, is provided at Attachment A. The medicines and PBS item codes included in Attachment A have all been recommended by the PBAC for inclusion in the increased MDQ measure.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of the consultation process the Department and Services Australia have collaborated on required information technology system changes, including to ensure that software vendors receive data outputs with sufficient time to ensure prescribing and dispensing software can be updated for the 1 March 2024 commencement of Stage 2 of the increased MDQ measure.

Incorporation by reference

The Instrument incorporates by reference the following legislative instruments, or provisions of the following legislative instruments:

- *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020;*
- *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017;*
- *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022;*
- *National Health (Listing of Pharmaceutical Benefits) Instrument 2012;*
- *National Health (Pharmaceutical Benefits) Regulations 2017.*

These instruments or relevant provisions of the instruments are all incorporated as in force from time to time and the instruments can be accessed free of charge on the Federal Register of Legislation at www.legislation.gov.au.

General

Details of the Instrument are at Attachment A.

This Instrument commences on 1 March 2024.

The human rights statement of compatibility is at Attachment B. The statement of compatibility concludes the Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003.*

ATTACHMENT A

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH LEGISLATION AMENDMENT (MAXIMUM DISPENSED QUANTITIES) INSTRUMENT 2024

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024* and may also be cited as PB 14 of 2024.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences on 1 March 2024.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

Schedule 1 of the Instrument amends Schedules 1 and 4 of the Main Listing Instrument to increase the maximum dispensed quantity (MDQ) for 238 PBS items. Schedule 1 will take effect on 1 March 2024. These items include some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis.

The MDQ is the maximum quantity or number of units of a pharmaceutical benefit that a PBS prescriber can direct to be supplied to a patient on the one occasion. The MDQ for the relevant items is currently an amount sufficient to one month's supply. Schedule 1 will amend the entries for the relevant items in Schedule 1 of the Main Listing Instrument to include a new MDQ, sufficient for two months' supply, along with the applicable new 'purposes codes' and 'circumstances codes'.

Schedule 1 of the Instrument will also amend Schedule 4 of the Main Listing Instrument to detail, for the new purposes and circumstances codes, the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient's condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME MADE BY SCHEDULE 1 OF THIS INSTRUMENT

Addition of Increased Maximum Dispensed Quantity

Drug	***Form (strength and presentation)***	***Item Code***
acarbose	acarbose 50 mg tablet, 90	08188Y
	acarbose 100 mg tablet, 90	08189B

Drug	*Form (strength and presentation)*	*Item Code*
alendronate with colecalciferol	alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4	09012H
	alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4	09183H
alogliptin	alogliptin 6.25 mg tablet, 28	02944Y
	alogliptin 12.5 mg tablet, 28	02933J
	alogliptin 25 mg tablet, 28	02986E
alogliptin with metformin	alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56	10033C
	alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56	10032B
	alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56	10035E
amlodipine with atorvastatin	amlodipine 10 mg + atorvastatin 80 mg tablet, 30	09056P
anastrozole	anastrozole 1 mg tablet, 30	08179L
bromocriptine	bromocriptine 2.5 mg tablet, 30	01443Y
cabergoline	cabergoline 500 microgram tablet, 8	08114C
carbamazepine	carbamazepine 100 mg/5 mL oral liquid, 300 mL	02427R
	carbamazepine 200 mg modified release tablet, 200	02426Q
	carbamazepine 400 mg modified release tablet, 200	02431Y
carbimazole	carbimazole 5 mg tablet, 100	01153Q
ciclosporin	ciclosporin 10 mg capsule, 60	08657P
	ciclosporin 25 mg capsule, 30	08658Q
	ciclosporin 50 mg capsule, 30	08659R
	ciclosporin 100 mg capsule, 30	08660T
	ciclosporin 100 mg/mL oral liquid, 50 mL	08661W
cortisone	cortisone acetate 5 mg tablet, 50	01246N
	cortisone acetate 25 mg tablet, 60	01247P
cyproterone	cyproterone acetate 50 mg tablet, 20	01269T
	cyproterone acetate 50 mg tablet, 50	01270W
	cyproterone acetate 100 mg tablet, 50	08019C
dapagliflozin	dapagliflozin 10 mg tablet, 28	10011X
	dapagliflozin 10 mg tablet, 28	12823X
dapagliflozin with metformin	dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56	10510E
	dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28	10516L
	dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28	10515K

Drug	*Form (strength and presentation)*	*Item Code*
desmopressin	desmopressin acetate 200 microgram tablet, 30	08662X
	desmopressin acetate 200 microgram tablet, 30	08663Y
	desmopressin 120 microgram sublingual wafer, 30	09398P
	desmopressin 240 microgram sublingual wafer, 30	08975J
dexamethasone	dexamethasone 500 microgram tablet, 30	01292B
dutasteride	dutasteride 500 microgram capsule, 30	05468T
dutasteride with tamsulosin	dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30	05490Y
empagliflozin	empagliflozin 10 mg tablet, 30	10206E
	empagliflozin 10 mg tablet, 30	12918X
	empagliflozin 25 mg tablet, 30	10202Y
empagliflozin with linagliptin	empagliflozin 10 mg + linagliptin 5 mg tablet, 30	11310G
	empagliflozin 25 mg + linagliptin 5 mg tablet, 30	11298P
empagliflozin with metformin	empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60	10626G
	empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60	10627H
	empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60	10633P
	empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60	10677Y
eprosartan	eprosartan 600 mg tablet, 28	05491B
	eprosartan 600 mg tablet, 28	08447N
estradiol	estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets	08286D
	estradiol 10 microgram modified release pessary, 18	10203B
	estradiol valerate 1 mg tablet, 56	01663M
	estradiol 2 mg tablet, 56	08274L
	estradiol valerate 2 mg tablet, 56	01664N
estradiol and estradiol with dydrogesterone	estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28	10146B
	estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28	08244X
estradiol and estradiol with norethisterone	estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8	08425K
	estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8	08426L
estradiol with norethisterone	estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8	08427M

Drug	*Form (strength and presentation)*	*Item Code*
estriol	estriol 0.1% (1 mg/g) cream, 15 g	01781R
	estriol 500 microgram pessary, 15	01771F
ethosuximide	ethosuximide 250 mg/5 mL oral liquid, 200 mL	01414K
everolimus	everolimus 750 microgram tablet, 60	08842J
	everolimus 1 mg tablet, 60	09352F
exemestane	exemestane 25 mg tablet, 30	08506Q
	exemestane 25 mg tablet, 30	10103R
glibenclamide	glibenclamide 5 mg tablet, 100	02939Q
gliclazide	gliclazide 60 mg modified release tablet, 60	09302N
	gliclazide 80 mg tablet, 100	02449X
glimepiride	glimepiride 1 mg tablet, 30	08450R
	glimepiride 2 mg tablet, 30	08451T
	glimepiride 3 mg tablet, 30	08533D
	glimepiride 4 mg tablet, 30	08452W
glipizide	glipizide 5 mg tablet, 100	02440K
hydrocortisone	hydrocortisone 4 mg tablet, 50	01499X
labetalol	labetalol hydrochloride 100 mg tablet, 100	01566K
lacosamide	lacosamide 10 mg/mL oral liquid, 200 mL	11694L
	lacosamide 10 mg/mL oral liquid, 200 mL	12628P
	lacosamide 50 mg tablet, 14	10293R
	lacosamide 50 mg tablet, 14	12626M
	lacosamide 100 mg tablet, 56	09335H
	lacosamide 100 mg tablet, 56	12634Y
	lacosamide 150 mg tablet, 56	09337K
	lacosamide 150 mg tablet, 56	12627N
	lacosamide 200 mg tablet, 56	09338L
	lacosamide 200 mg tablet, 56	12658F
lamotrigine	lamotrigine 5 mg tablet, 56	08063J
	lamotrigine 25 mg tablet, 56	02848X
	lamotrigine 50 mg tablet, 56	02849Y
	lamotrigine 100 mg tablet, 56	02850B
	lamotrigine 200 mg tablet, 56	02851C
lanthanum	lanthanum 500 mg chewable tablet, 2 x 45	09403X
	lanthanum 750 mg chewable tablet, 6 x 15	09404Y
	lanthanum 1 g chewable tablet, 6 x 15	09405B
leflunomide	leflunomide 10 mg tablet, 30	05449T

Drug	*Form (strength and presentation)*	*Item Code*
	leflunomide 10 mg tablet, 30	08374R
	leflunomide 20 mg tablet, 30	05450W
	leflunomide 20 mg tablet, 30	08375T
letrozole	letrozole 2.5 mg tablet, 30	08245Y
levetiracetam	levetiracetam 100 mg/mL oral liquid, 300 mL	09169N
	levetiracetam 250 mg tablet, 60	08654L
	levetiracetam 500 mg tablet, 60	08655M
	levetiracetam 1 g tablet, 60	08656N
linagliptin	linagliptin 5 mg tablet, 30	03387G
linagliptin with metformin	linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60	10038H
	linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60	10045Q
	linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60	10044P
liothyronine	liothyronine sodium 20 microgram tablet, 100	02318B
medroxyprogesterone	medroxyprogesterone acetate 5 mg tablet, 56	02323G
	medroxyprogesterone acetate 10 mg tablet, 100	02722G
	medroxyprogesterone acetate 10 mg tablet, 30	02321E
	medroxyprogesterone acetate 100 mg tablet, 100	02725K
	medroxyprogesterone acetate 200 mg tablet, 60	02316X
	medroxyprogesterone acetate 250 mg tablet, 60	02727M
	medroxyprogesterone acetate 500 mg tablet, 30	02728N
metformin	metformin hydrochloride 500 mg modified release tablet, 120	09435N
	metformin hydrochloride 500 mg tablet, 100	02430X
	metformin hydrochloride 850 mg tablet, 60	01801T
	metformin hydrochloride 1 g modified release tablet, 60	03439B
	metformin hydrochloride 1 g tablet, 90	08607B
methenamine	methenamine hippurate 1 g tablet, 100	03124K
methotrexate	methotrexate 50 mg/2 mL injection, 5 x 2 mL vials	02395C
minoxidil	minoxidil 10 mg tablet, 100	02313R
mycophenolate	mycophenolate mofetil 250 mg capsule, 50	01836P
	mycophenolate mofetil 250 mg capsule, 100	08649F
	mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL	08651H
	mycophenolate 180 mg enteric tablet, 120	02150E
	mycophenolate 360 mg enteric tablet, 120	02193K
	mycophenolate mofetil 500 mg tablet, 50	08650G

Drug	*Form (strength and presentation)*	*Item Code*
norethisterone	norethisterone 5 mg tablet, 30	02993M
olmesartan with amlodipine	olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30	05293N
	olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30	05294P
olmesartan with amlodipine and hydrochlorothiazide	olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30	02953K
oxcarbazepine	oxcarbazepine 60 mg/mL oral liquid, 250 mL	08588B
	oxcarbazepine 300 mg tablet, 100	08585W
	oxcarbazepine 600 mg tablet, 100	08586X
oxybutynin	oxybutynin 3.9 mg/24 hours patch, 8	09454N
	oxybutynin hydrochloride 5 mg tablet, 100	08039D
perampanel	perampanel 4 mg tablet, 28	10162W
	perampanel 4 mg tablet, 28	11418Y
	perampanel 6 mg tablet, 28	10163X
	perampanel 6 mg tablet, 28	11407J
	perampanel 8 mg tablet, 28	10160R
	perampanel 8 mg tablet, 28	11429M
	perampanel 10 mg tablet, 28	10151G
	perampanel 10 mg tablet, 28	11428L
	perampanel 12 mg tablet, 28	10159Q
	perampanel 12 mg tablet, 28	11409L
phenoxymethylpenicillin	phenoxymethylpenicillin 250 mg capsule, 50	01705R
	phenoxymethylpenicillin 250 mg tablet, 25	01703P
phenytoin	phenytoin sodium 30 mg capsule, 200	01873N
	phenytoin sodium 100 mg capsule, 200	01874P
	phenytoin 30 mg/5 mL oral liquid, 500 mL	02692Q
	phenytoin 50 mg chewable tablet, 200	01249R
phosphorus	phosphorus 500 mg effervescent tablet, 100	02946C
pioglitazone	pioglitazone 15 mg tablet, 28	08694N
	pioglitazone 30 mg tablet, 28	08695P
	pioglitazone 45 mg tablet, 28	08696Q
pizotifen	pizotifen 500 microgram tablet, 100	03074T
prednisolone	prednisolone 1 mg tablet, 100	03152X
	prednisolone 5 mg tablet, 60	01917X
	prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL	08285C

Drug	*Form (strength and presentation)*	*Item Code*
prednisone	prednisone 1 mg tablet, 100	01934T
	prednisone 5 mg tablet, 60	01935W
probenecid	probenecid 500 mg tablet, 100	01940D
propantheline	propantheline bromide 15 mg tablet, 100	01953T
propylthiouracil	propylthiouracil 50 mg tablet, 100	01955X
quinagolide	quinagolide 75 microgram tablet, 30	08822H
saxagliptin	saxagliptin 2.5 mg tablet, 28	10128C
	saxagliptin 5 mg tablet, 28	08983T
saxagliptin with dapagliflozin	saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28	11305B
saxagliptin with metformin	saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56	10048W
	saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28	10055F
	saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28	10051B
sevelamer	sevelamer carbonate 800 mg tablet, 180	11856B
	sevelamer hydrochloride 800 mg tablet, 180	02142R
sirolimus	sirolimus 1 mg/mL oral liquid, 60 mL	08725F
	sirolimus 500 microgram tablet, 100	08984W
	sirolimus 1 mg tablet, 100	08724E
	sirolimus 2 mg tablet, 100	08833X
sitagliptin	sitagliptin 25 mg tablet, 28	09180E
	sitagliptin 50 mg tablet, 28	09181F
	sitagliptin 100 mg tablet, 28	09182G
sitagliptin with metformin	sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56	09449H
	sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56	09450J
	sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56	10090C
	sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56	09451K
	sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28	10089B
sodium bicarbonate	sodium bicarbonate 840 mg capsule, 100	09470K
spironolactone	spironolactone 100 mg tablet, 100	02340E
sucroferric oxyhydroxide	sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90	10250L
sulthiame	sulthiame 50 mg tablet, 200	02099L

Drug	*Form (strength and presentation)*	*Item Code*
	sulthiame 200 mg tablet, 200	02100M
tacrolimus	tacrolimus 500 microgram capsule, 100	08646C
	tacrolimus 500 microgram modified release capsule, 30	05299X
	tacrolimus 750 microgram capsule, 100	10870D
	tacrolimus 1 mg capsule, 100	08647D
	tacrolimus 1 mg modified release capsule, 60	05300Y
	tacrolimus 2 mg capsule, 100	10871E
	tacrolimus 3 mg modified release capsule, 50	11914C
	tacrolimus 5 mg capsule, 50	08648E
	tacrolimus 5 mg modified release capsule, 30	05451X
tamoxifen	tamoxifen 20 mg tablet, 30	01880Y
	tamoxifen 20 mg tablet, 30	10911G
	tamoxifen 20 mg tablet, 60	02110C
teriparatide	teriparatide 250 microgram/mL injection, 2.4 mL cartridge	12670W
testosterone	testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations	10380H
	testosterone 2% (23 mg/actuation) gel, 56 actuations	11740X
	testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets	08830R
tiagabine	tiagabine 5 mg tablet, 50	08221Q
	tiagabine 10 mg tablet, 50	08222R
	tiagabine 15 mg tablet, 50	08223T
tobramycin	tobramycin 28 mg powder for inhalation, 224 capsules	10074F
	tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules	05442K
topiramate	topiramate 15 mg capsule, 60	08371N
	topiramate 25 mg capsule, 60	08372P
	topiramate 50 mg capsule, 60	08520K
	topiramate 25 mg tablet, 60	08163P
	topiramate 50 mg tablet, 60	08164Q
	topiramate 100 mg tablet, 60	08165R
	topiramate 200 mg tablet, 60	08166T
toremifene	toremifene 60 mg tablet, 30	08216K
valproic acid	valproate sodium 200 mg/5 mL oral liquid, 300 mL	02293Q
	valproate sodium 200 mg/5 mL oral liquid, 300 mL	02295T
	valproate sodium 100 mg tablet, 100	02294R
	valproate sodium 200 mg enteric tablet, 100	02289L
	valproate sodium 500 mg enteric tablet, 100	02290M

Drug	*Form (strength and presentation)*	*Item Code*
vigabatrin	vigabatrin 500 mg powder for oral liquid, 60 sachets	02668K
	vigabatrin 500 mg tablet, 100	02667J
vildagliptin	vildagliptin 50 mg tablet, 60	03415R
vildagliptin with metformin	vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60	05474D
	vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60	05475E
	vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60	05476F
zonisamide	zonisamide 25 mg capsule, 56	09388D
	zonisamide 50 mg capsule, 56	09389E
	zonisamide 100 mg capsule, 56	09390F

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
dapagliflozin empagliflozin topiramate	**Approved Product Information/Australian Product Information/TGA-approved Product Information.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
dapagliflozin empagliflozin	**New York Heart Association (NYHA) classification** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The NYHA classification system is used to define the degree of heart failure.	The NYHA classification system is available for download for free from the Heart Foundation website (contained within the heart failure clinical guidelines): https://www.heartfoundation.org.au/Conditions/Heart-failure-clinical-guidelines

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024

(PB 14 of 2024)

This Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Instrument

National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024 (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

On 1 March 2024 the Principal Instrument will be amended by Schedule 1 to the Instrument to implement stage 2 of the maximum dispensed quantity (MDQ) measure. The MDQ measure increases the maximum quantity that may be prescribed to be dispensed on one occasion for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS.

The amendments made by the Instrument are the second of three stages of implementation of the MDQ measure. Stage 2 includes some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis. Patients will only be eligible to receive an increased supply where their chronic condition is stable.

Current listings enabling the prescription of one month's supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based.

Stage 2 of the MDQ measure will be implemented on 1 March 2024 by amendments to the Principal Instrument made by the *National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024.* A detailed analysis of the human rights implications of the MDQ measure is included in the Statement of Compatibility with Human Rights in the Explanatory Statement for the instrument which implemented stage 1 of the MDQ measures on 1 September 2023, which can be found on the Federal Register of Legislation at *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*. However, the overall policy behind the MDQ measure is to address the affordability of medicines and the cost-of-living pressures many Australians are currently facing. The MDQ increases the amount of drugs that eligible patients can receive for a single co-payment, which allows for greater patient access to these drugs, convenience and financial savings. The lowering of costs to patients is likely to have a positive impact on patient medication compliance and associated health outcomes.

Addition of new purposes and circumstances codes does not affect human rights. The new purposes and circumstances codes detail the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient's condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Implementation of the MDQ measure does not risk exacerbating any shortages of these medicines in the community as a whole. It should be noted that before making the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023,* the Minister sought advice from the PBAC who noted that the number of patients and volume of medicines prescribed will not change significantly as a result of the MDQ measure and that any medicine shortages were likely to be short-term as the system adjusts to a new phased model of supply.

The Therapeutic Goods Administration (TGA) works with many stakeholders to manage shortages and can take a range of actions to assist with medicine shortages. These actions are discussed in detail in the Statement of Compatibility with Human Rights in the Explanatory Statement for the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* but include approving the supply of overseas-registered alternative products under section 19A of the *Therapeutic Goods Act 1989*, working with key stakeholders to manage inventory, including constraining supply to enable fair distribution of stock in Australia and implementing a Serious Scarcity Substitution Instrument, which allows pharmacists to dispense certain identified substitute medicines when a medicine is in shortage. Pharmacists and prescribers already manage medicine supply shortages in a number of ways on a daily basis.

Where there are many brands of a listed drug and form, then the removal of one brand from the increased MDQ measure will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The removal of brands from the increased MDQ measure in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the removal of brands from the increased MDQ measure in this instrument do not result in an unmet clinical need.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care